

House File 2389 - Introduced

HOUSE FILE _____
BY PETERSEN

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act relating to the creation of a postnatal tissue and fluid
2 banking network, and including the creation of an oversight
3 commission.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
5 TLSB 5897YH 82
6 pf/nh/5

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1 1 Section 1. NEW SECTION. 1350.1 DEFINITIONS.
1 2 As used in this chapter, unless the context otherwise
1 3 requires:
1 4 1. "Amniotic fluid" means the fluid inside the amnion.
1 5 2. "Birthing hospital" means a private or public hospital
1 6 licensed pursuant to chapter 135B that has a licensed
1 7 obstetric unit or is licensed to provide obstetric services.
1 8 3. "Commission" means the postnatal tissue and fluid
1 9 banking oversight commission established pursuant to section
1 10 1350.3.
1 11 4. "Cord blood" means human blood from the placenta and
1 12 umbilical cord collected after the umbilical cord has been
1 13 detached from the newborn child.
1 14 5. "Department" means the department of public health.
1 15 6. "Iowa hematopoietic stem cell bank" or "Iowa bank"
1 16 means the Iowa hematopoietic stem cell bank of the university
1 17 of Iowa hospitals and clinics.
1 18 7. "Placenta" means the organ that forms on the inner wall
1 19 of the human uterus during pregnancy.
1 20 8. "Postnatal tissue and fluid" means the placenta,
1 21 umbilical cord, and amniotic fluid expelled or extracted in
1 22 connection with the birth of a child.
1 23 9. "Regional perinatal center" means a regional perinatal
1 24 center established by the statewide perinatal care program.
1 25 10. "Statewide perinatal care program" means the statewide
1 26 perinatal care program under the department of public health,
1 27 that provides professional training, development of standards
1 28 and guidelines of care, consultation to regional and primary
1 29 providers, and evaluation of the quality of care delivered to
1 30 reduce the mortality and morbidity of infants through a
1 31 contract with the university of Iowa hospitals and clinics.
1 32 11. "Umbilical cord" means the gelatinous tissue and blood
1 33 vessels connecting an unborn human being to the placenta.
1 34 Sec. 2. NEW SECTION. 1350.2 POSTNATAL TISSUE AND FLUID
1 35 BANKING NETWORK.
2 1 1. The department shall establish a postnatal tissue and
2 2 fluid banking network to collect, process, store, and provide
2 3 for the disposition of stored specimens for therapeutic stem
2 4 cell medical treatments and stem cell research. The network
2 5 shall include all of the following:
2 6 a. Birthing hospitals in the state as voluntary collection
2 7 sites.
2 8 b. The Iowa hematopoietic stem cell bank, which shall be
2 9 expanded, statewide, to provide for the testing of specimens
2 10 collected to determine if the specimen is eligible for
2 11 transplant or research. Specimens eligible for research shall
2 12 also be stored by the Iowa bank.
2 13 c. A partnership with a regional cord blood bank for
2 14 storage of specimens determined to be eligible for
2 15 transplantation and for entry of information regarding the
2 16 specimens into appropriate national and international
2 17 registries.
2 18 2. The Iowa hematopoietic stem cell bank shall provide
2 19 birthing hospitals with training regarding the collection of

2 20 postnatal tissue and fluids. The Iowa bank shall offer
2 21 participating birthing hospitals the option of collecting
2 22 specimens for transportation to the Iowa bank via courier
2 23 service. Quality assurance shall be monitored by the
2 24 statewide perinatal care program as part of regularly
2 25 scheduled birthing hospital site visits. Initially, specimen
2 26 collection shall focus on the collection of cord blood. At
2 27 such time as other postnatal tissue or fluids are collected,
2 28 procedures for collection shall be developed and organized
2 29 through the regional perinatal centers as primary collection
2 30 sites. Training regarding the collection of these other
2 31 postnatal tissue or fluids shall be provided to the regional
2 32 perinatal centers by the Iowa bank and the regional perinatal
2 33 centers shall in turn provide training to the birthing
2 34 hospitals in their regions.

2 35 3. Birthing hospitals and health care providers shall
3 1 promote and encourage the donation of postnatal tissue and
3 2 fluid through education, public awareness, and the removal of
3 3 barriers to donation.

3 4 a. Birthing hospitals and health care providers shall
3 5 inform potential donors no later than the beginning of the
3 6 third trimester of a pregnancy, of the options to donate to
3 7 either private banking programs or to the Iowa bank.

3 8 b. Potential donors, at a minimum, shall be informed of
3 9 all of the following:

3 10 (1) The current and potential future medical uses of
3 11 postnatal tissue and fluids.

3 12 (2) The benefits and risks associated with postnatal
3 13 tissue and fluid banking.

3 14 (3) Medical or family history criteria that may impact a
3 15 family's consideration of postnatal tissue and fluid banking.

3 16 (4) An explanation of the differences between private and
3 17 public banking. Potential donors shall be informed that
3 18 donated specimens may be purchased by companies for commercial
3 19 use.

3 20 (5) Medically-accepted uses and benefits of postnatal
3 21 tissue and fluid collection and transplantation.

3 22 (6) The costs associated with donation and storage, and an
3 23 explanation of the storage, maintenance, and viability of
3 24 transplantation of postnatal tissue and fluid.

3 25 c. Donation shall be promoted on a voluntary basis and
3 26 birthing hospitals and providers shall work with the network
3 27 to ensure that there is no cost to the donor for collection of
3 28 donated specimens, unless the donation is a directed donation
3 29 of cord blood to be stored for personal use.

3 30 4. The postnatal tissue and fluid banking network shall
3 31 develop a state postnatal tissue and fluid bank database to
3 32 maintain information regarding specimens collected and stored
3 33 for the purposes of research. The database shall utilize a
3 34 web-based format, have the capacity to search multiple
3 35 databases, deliver search results by encrypted electronic
4 1 mail, maintain patient records, and generate reports for
4 2 quality assurance and quality improvement purposes.

4 3 5. The postnatal tissue and fluid banking network shall
4 4 partner with a regional cord blood bank for the purposes of
4 5 providing specimens for transplantation and maintaining
4 6 information regarding clinically useful cord blood specimens
4 7 to link with national and international registries. Following
4 8 testing, specimens collected from birthing hospitals and
4 9 health care providers in the state that are determined to be
4 10 eligible for transplantation shall be sent to the regional
4 11 cord blood bank for storage. The partnership agreement shall
4 12 require that the specimens sent to the regional blood bank
4 13 shall be stored by the regional blood bank and that
4 14 information regarding clinically useful cord blood specimens
4 15 shall be maintained by the regional bank and also linked with
4 16 and entered into appropriate national and international
4 17 registries. Specimens determined not eligible for
4 18 transplantation shall be stored at the Iowa bank and made
4 19 available for research.

4 20 6. Specimens collected shall not be used for creation of
4 21 stem cells for reproductive cloning.

4 22 7. The postnatal tissue and fluid banking network shall
4 23 comply and coordinate with all requirements for certification
4 24 by all national and federal entities as specified by rule of
4 25 the postnatal tissue and fluid banking oversight commission.

4 26 8. All research conducted by any member of the network
4 27 shall be subject to approval of an institutional review board
4 28 that is established in accordance with federal and state
4 29 regulations. Distribution of specimens for research shall
4 30 also meet all rules adopted by the commission for such

4 31 distribution.

4 32 9. The postnatal tissue and fluid banking network shall
4 33 comply with all rules adopted by the commission including
4 34 those related to consent, privacy, and the fee structure.

4 35 Sec. 3. NEW SECTION. 1350.3 POSTNATAL TISSUE AND FLUID
5 1 BANKING OVERSIGHT COMMISSION.

5 2 1. The department shall convene and provide administrative
5 3 support to a postnatal tissue and fluid banking oversight
5 4 commission.

5 5 2. The commission shall consist of the following members,
5 6 selected by the institution or association specified or, if
5 7 not specified, selected by the director of public health:

5 8 a. The director of public health, or the director's
5 9 designee.

5 10 b. A representative of each of the public and private
5 11 colleges or universities in the state that have interest in
5 12 postnatal tissue and fluid for the purposes of research or
5 13 medical treatment.

5 14 c. A representative of the Iowa hospital association.

5 15 d. A representative of the Iowa osteopathic medical
5 16 association.

5 17 e. A representative of the Iowa medical society.

5 18 f. A physician representing a birthing hospital.

5 19 g. A prenatal health care provider.

5 20 h. A representative of the Iowa midwives association.

5 21 i. A representative of the postnatal tissue and fluid
5 22 research community.

5 23 j. A representative of recipients of postnatal tissue and
5 24 fluid transplants.

5 25 k. A representative of a postnatal tissue and fluid
5 26 transplant center.

5 27 l. A representative of a postnatal tissue and fluid bank.

5 28 m. An attorney with expertise in public health or
5 29 biotechnology law, selected by the Iowa state bar association.

5 30 n. A recognized medical ethicist who has an accredited
5 31 degree in medicine, medical ethics, or theology.

5 32 3. Members of the commission shall serve terms of three
5 33 years, beginning and ending as provided in section 69.19.

5 34 Vacancies shall be filled by the original appointing authority
5 35 and in the manner of the original appointment. Members shall

6 1 receive reimbursement for actual expenses incurred while
6 2 serving in their official capacity and may also be eligible to
6 3 receive compensation as provided in section 7E.6. A person
6 4 appointed to fill a vacancy for a member shall serve only for
6 5 the unexpired portion of the term. A member is eligible for
6 6 reappointment for two successive terms.

6 7 4. The commission shall meet at least quarterly and at the
6 8 call of the chairperson. A majority of the members
6 9 constitutes a quorum. Any action taken by the commission must
6 10 be adopted by the affirmative vote of a majority of the
6 11 members.

6 12 5. The commission shall do all of the following:

6 13 a. Develop regulations, protocols and policies, public
6 14 reporting requirements, research requirements, and fiscal
6 15 auditing and accountability measures relative to postnatal
6 16 tissue and fluid banking in the state and in partnership with
6 17 entities outside of the state with interest in postnatal
6 18 tissue and fluid banking.

6 19 b. Establish an advisory council to address ongoing
6 20 ethical, legal, and intellectual property issues.

6 21 c. Oversee the statewide expansion of the Iowa
6 22 hematopoietic stem cell bank and the development of a
6 23 partnership with an existing regional cord blood bank to
6 24 maintain specimens eligible for transplantation.

6 25 d. Promote the development of a network of birthing
6 26 hospitals in the state for the voluntary collection of cord
6 27 blood and other postnatal tissue and fluids.

6 28 e. Develop criteria for the distribution of specimens for
6 29 research and medical treatment. Specimens shall be available
6 30 to both private and public researchers. Fees for research
6 31 specimens shall be incurred by the research organization and
6 32 shall be standard and comparable to the charges levied by
6 33 similar tissue and fluid banks.

6 34 f. Provide for the collection of information regarding
6 35 postnatal tissue and fluid banking specimens. Information on
7 1 clinically useful cord blood specimens shall be maintained by
7 2 the regional cord blood bank with which the state partners to
7 3 maintain specimens eligible for transplantation and to enter
7 4 such specimens on national and international registries. The
7 5 state postnatal tissue and fluid bank database developed
7 6 pursuant to section 1350.2, subsection 4, shall maintain

7 7 information on specimens collected for the purpose of
7 8 research.
7 9 g. Promote and encourage voluntary donation of postnatal
7 10 tissue and fluid through education, public awareness, and the
7 11 removal of barriers to donation. To the extent possible, the
7 12 commission shall seek approval to utilize existing educational
7 13 and awareness materials as a basis for development of
7 14 state-specific materials.
7 15 h. Provide for consent and privacy protections for persons
7 16 who donate postnatal tissue and fluid. The protections shall
7 17 be consistent with applicable federal guidelines and shall
7 18 address the collection, retention, use, and disposition of
7 19 specimens, as well as ownership rights to the specimens. The
7 20 protections shall require that all specimens released for
7 21 transplant or research shall not contain any identifying
7 22 information upon release so as to protect from disclosure the
7 23 identity of persons making donations to the state or regional
7 24 bank.
7 25 i. Provide a fee structure for participation in the state
7 26 postnatal tissue and fluid banking network. The fee structure
7 27 shall be based on the use of the specimen stored. If the
7 28 specimen is to be used for medical treatment, fees shall be
7 29 imposed consistent with requirements of the regional bank. If
7 30 the specimen is used for research, fees shall be charged to
7 31 the entity managing the research project. Any costs incurred
7 32 by the research entity to obtain institutional review board
7 33 approval or to meet other requirements for project approval
7 34 shall be the responsibility of the research entity.
7 35 j. Report to the governor and the general assembly in
8 1 December, annually, concerning the activities of the network
8 2 and the commission with recommendations for any legislative
8 3 changes or funding necessary to fulfill the goals of this
8 4 chapter.
8 5 k. Request additional funding from any additional source
8 6 including but not limited to federal and private grants.
8 7 l. Review research request policies for consistency with
8 8 other programs including but not limited to those policies
8 9 established by the center for congenital and inherited
8 10 disorders established pursuant to section 136A.3.

8 11 EXPLANATION

8 12 This bill relates to postnatal tissue and fluid banking.
8 13 The bill establishes a postnatal tissue and fluid banking
8 14 network to collect, process, store, and provide for the
8 15 disposition of stored specimens for therapeutic stem cell
8 16 medical treatments and stem cell research. The network
8 17 includes birthing hospitals in the state as voluntary
8 18 collection sites; the Iowa hematopoietic stem cell bank at the
8 19 university of Iowa hospitals and clinics, which is to be
8 20 expanded, statewide, to provide for the testing of specimens
8 21 collected to determine if the specimen is eligible for
8 22 transplant or research, with specimens eligible for research
8 23 to also be stored by the Iowa bank; and a partnership with a
8 24 regional blood bank for storage of specimens determined to be
8 25 eligible for transplantation and for entry of information
8 26 regarding these specimens into appropriate national and
8 27 international registries.

8 28 The bill directs the Iowa hematopoietic stem cell bank to
8 29 provide birthing hospitals with training regarding collection
8 30 of postnatal tissue and fluids. Participating birthing
8 31 hospitals may transport specimens collected to the Iowa bank
8 32 via courier service. Quality assurance is to be provided by
8 33 the statewide perinatal care program. Initially, specimen
8 34 collection shall focus on collection of umbilical cord blood.
8 35 At such time as other postnatal tissue or fluids are
9 1 collected, procedures for collection shall be developed and
9 2 organized through the regional perinatal centers as primary
9 3 collection sites.

9 4 The bill directs birthing hospitals and providers to
9 5 promote and encourage the donation of postnatal tissue and
9 6 fluid through education, public awareness, and the removal of
9 7 barriers to donation. The bill specifies information that, at
9 8 a minimum, is to be provided to potential donors no later than
9 9 the beginning of the third trimester of a pregnancy, regarding
9 10 options to donate to either private banking programs or to the
9 11 Iowa bank. Donation is on a voluntary basis and birthing
9 12 hospitals and providers are to work with the network to ensure
9 13 that there is no cost to the donor for collection of donated
9 14 specimens, unless the donation is a directed donation of cord
9 15 blood to be stored for personal use.

9 16 The bill directs the postnatal tissue and fluid banking
9 17 network to develop a state postnatal tissue and fluid bank

9 18 database to maintain information regarding specimens collected
9 19 and stored for the purposes of research and to partner with a
9 20 regional cord blood bank for the purposes of providing
9 21 specimens for transplantation and maintaining information
9 22 regarding clinically useful cord blood specimens to link with
9 23 national and international registries. The bill prohibits
9 24 specimens collected from being used for creation of stem cells
9 25 for reproductive cloning.

9 26 All research conducted by any member of the network is
9 27 subject to approval of an institutional review board, and
9 28 distribution of specimens for research shall also meet all
9 29 rules adopted by the postnatal tissue and fluids banking
9 30 oversight commission for such distribution.

9 31 The bill also directs the department of public health to
9 32 convene and provide administrative support to a postnatal
9 33 tissue and fluid banking oversight commission. The bill
9 34 specifies the membership of the commission, the terms of
9 35 appointments, meetings of the commission, and other procedural
10 1 requirements. The duties of the commission include:
10 2 developing regulations, protocols and policies, public
10 3 reporting requirements, research requirements, and fiscal
10 4 auditing and accountability measures relative to postnatal
10 5 tissue and fluid banking in the state and in partnership with
10 6 entities outside of the state with interest in postnatal
10 7 tissue and fluid banking; establishing an advisory council to
10 8 address ongoing ethical, legal, and intellectual property
10 9 issues; overseeing the statewide expansion of the Iowa
10 10 hematopoietic stem cell bank and the development of a
10 11 partnership with an existing regional cord blood bank to
10 12 maintain specimens eligible for transplantation; promoting the
10 13 development of a network of birthing hospitals in the state
10 14 for the voluntary collection of umbilical cord blood and other
10 15 postnatal tissue and fluids; developing criteria for the
10 16 distribution of specimens for research and medical treatment;
10 17 providing for the collection of information regarding
10 18 postnatal tissue and fluid banking specimens; promoting and
10 19 encouraging voluntary donation of postnatal tissue and fluid
10 20 through education, public awareness, and the removal of
10 21 barriers to donation; providing for consent and privacy
10 22 protections for persons who donate postnatal tissue and fluid;
10 23 providing a fee structure for participation in the state
10 24 postnatal tissue and fluid banking network; reporting to the
10 25 governor and the general assembly annually; requesting
10 26 additional funding from any additional source including but
10 27 not limited to federal and private grants; and reviewing
10 28 research request policies for consistency with other programs.
10 29 LSB 5897YH 82
10 30 pf/nh/5